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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,126	03/09/2001	Alan R. Brooks	15303-000310	8941

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EXAMINER	
LIU, SAMUEL W	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/803,126	BROOKS ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication app ars on the cov r she t with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 40-42* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 40-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DTAILED ACTION

Applicants' amendment filed 15 September 2003, which amends claims 1-2, 4-5 and 8 and adds claims 40-42, and, applicants' request for extension of time of three months filed 15 September 2003 have been entered. The following pending claims 1-11 and 40-42 are examined in this Office action.

Please note that grounds of objection and/or rejection not explicitly restated and/or set forth below are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 and 40-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current disclosure does not provide written description for nucleic acids encoding polypeptide that shares at least 70%, 80%, 90% or 95% sequence identity to the full-length sequence SEQ ID NO: 2, 5 or 7; such the claim language encompasses a large number of polynucleotide fragments, variants and overlapping derivatives *etc.* The specification does not provide any functions associated with these variants. Without providing correlation of structure with function, the skilled artisan cannot know if the specification describes a polynucleotide

encoding the variant polypeptides. For example, a nucleic acid encoding a polypeptide which shares ≥ 70% sequence identity with the polypeptide of SEQ ID NO: 1, 4 or 6 can be an antagonist that has a function not disclosed or described in the specification. Therefore, the specification does not provide written description of the claimed nucleic acid molecules encoding variant polypeptides.

Applicant is in possession of nucleic acid molecule of the full-length polynucleotide SEQ ID NOs: 2, 5 and 7 which encode the polypeptide SEQ ID NOs: 1, 4 and 6, respectively. Applicant is not in possession of (i) any isolated nucleotide sequences encoding the amino acid sequences that are at least 70% (claim 1), 80% (claim 40), or 95% (claim 41) identical to the full-length polypeptides of SEQ ID NOs: 1, 4 or 6, respectively (note that any structural alterations in polypeptide level are unpredictable in respect to biological functions); (ii) any isolated nucleic acid molecule comprising a nucleotide sequence that encodes the polypeptides SEQ ID NOs: 1, or 4, or 6 in the claims 3 (note that, herein, the "*comprising*" is open language, which introduces unknown portion(s) of nucleotide sequence besides the portion of the full-length polynucleotide encoding polypeptide of SEQ ID NO: 1, or 4 or 6); and (iii) any polynucleotide sequence comprising a nucleotide sequence that is at least 80 % (claim 4) or 90% (claim 5) or 95% (claim 42) identical to SEQ ID NO:2 or 3, or 5 or 7, respectively (note that, herein, the "*comprising*" is open language as opposed to "consisting of", which renders the claim so broader that they encompasses any nucleotide sequence apart from the recited nucleotide sequences of 80% or 90% or 95% identity to the full-length sequence of SEQ ID NO:2 or 3, or 5 or 7). The specification does not provide guidance or teaching or working examples in this regard. Thus, applicants are not in possession of the claimed polynucleotides.

Also, the specification does not provide written description regarding a polynucleotide encoding a polypeptide having characteristic of specifically binding to polyclonal antibodies against a polypeptide comprising SEQ ID NO: 1 or 4 or 6 (see the instant claim 1). Neither is antibody binding seen as sufficiently limiting since an antibody epitope may be as small as 6-15 shared amino acid residues and places no limitations on the function of the protein containing the polypeptide sequence recognized. Thus, in the absence of *a testable function* and limitations regarding the sequence length over which the antigenicity identity is required, such the claim language does not allow skilled artisan one of skill in the art to make and use the claimed polynucleotide encoding a peptide epitope. Thus, applicants are not in possession of the claimed nucleic acid thereof.

Claims of the instant application recite that an isolated polynucleotide encoding polypeptide that is at least 70% identical to full-length SEQ ID NO: 1 or 4 or 6. The claims as written have variations up to 30% at protein level. Such recitation does not require that the full length of the nucleotide sequence of SEQ ID NO: 2, or 5 or 7 that encodes SEQ ID NO: 1 or 4 or 6 but rather encompasses numerous nucleotide sequences that encoding polypeptide variants of which there are partial-functional or malfunctional molecules, absent of factual indicia to the contrary.

The specification does not describe representative example(s) or/and the consequence of the variants and their use in investigating tissue-specific and estrogen receptor-specific agonist and antagonist, and fails to describe the common attributes or characteristics that identify any polynucleotide variants. The specification is thus insufficient to enable skilled artisan to practice the invention as broadly claimed without an undue amount of experimentation.

Making changes up to 30%, or, even more than 30% (due to the claim recitation "*70% amino acid sequence identity to* ") of a polypeptide sequence does not provide maintaining the same three dimensional structure as the 100% identity over the full length polypeptides SEQ ID NOs: 1, 4 and 6 that are encoded by polynucleotide SEQ ID NO: 2 or 5 or 7. Thus, the instant claim language appears to encompass all possible subsequences of polynucleotide and polypeptide without regarding structure-function relationship. This would create numerous variants (sequences) that are unpredictable on both structure and function.

The current claim language encompasses a large number of the polynucleotide variants that are both structurally and functionally deviated from the disclosed full-length polynucleotides SEQ ID NO: 2, 5 and 7. One of skill in the art would reasonably conclude that the disclosure insufficiently provides written description regarding the biological activity or role(s) of the claimed polynucleotide variants. The specification provides insufficient guidance and no working examples as to how to make and use of the variant molecules, e.g., use of the variant(s) in pharmacology for investigating tissue-specific and estrogen-receptor specific agonists or antagonists (see page 7, the first paragraph).

Applicants have disclosed only the full-length nucleic acids of SEQ ID NOs: 2, 3, 5 and 7; therefore, the skilled artisan cannot envision all the contemplated nucleic acid sequence possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993).

Description of invention's reduction to practice, unaccompanied by any meaningful, distinguishing characteristics of evolved the polynucleotide variants, i.e., the variant encoding polypeptide of 70% identity to the corresponding full-length polypeptide is insufficient to satisfy written description requirement of 35 U.S.C. §112, since, in context of present case, disclosure of manner in which invention was reduced to practice does not satisfy more fundamental written description requirement set forth in Section 112.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Response to the rejection under 35 USC 112, the first paragraph

The response (filed 15 September 2003) asserts that applicants are in possession of the claimed nucleic acids as sequence alignment (BLAST2) shows that aligned human and mouse MRP amino acid sequences share 74% identity [*SEQ ID NO:1 versus SEQ ID NO:4*] (see page 10, the first paragraph). The applicants' argument is unpersuasive because of the following at least two reasons. (1) 30% variation of polypeptide of SEQ ID NO:1 (full-length: 1,337 amino acids) would account for a polypeptide fragment consisting of 401 contiguous amino acids in length; insertion or deletion of such the polypeptide fragment of 401 residues, or insertion or deletion or substitution *via* any combinations of 401 amino acids, which are scattered within the subject polypeptide molecule, is highly unpredictable in both structure and function. (2) since the specification does not provide any factual evidence for identifying and characterizing the core sequence which is critical for the polypeptide activity, the recitation based solely upon

theoretical sequence alignment is insufficient for identifying the polynucleotide encoding the polypeptide that would retain bioactivity of the respective full-length protein after 30% structural variations – insertion, deletion or/and substitution.

Also, the response argues that the current disclosure provides description for the claimed composition as the specification (page 10, lines 11-14) sets forth that 70-95% amino acid identity is resulted from a polymorphic variant, or allele of the MRP protein (see page 10, the second paragraph). The argument is not persuasive because the said variants in the specification (page 10, lines 11-14) refer to those made by comparing a peptide sequence of about 25 amino acid or 50-100 amino acids but NOT the full-length MRP polypeptide. It is noted that the current invention is directed to the polynucleotides SEQ ID NO: 2, 3, 5, and 7, not to small fragment or portion thereof.

Claim Rejections - 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 40-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang, A. et al. (*Science* (1998) 280, 1447-1451).

Wang et al. teach an isolated nucleic acid molecule from chromosome 17 (human) which comprises genes encoding unconventional myosin proteins, as applied to claims 1-8 and 40-42 of the current application.

Please note that the specification sets forth that polynucleotide encoding a myosin-related protein (MRP) of the current invention is mapped to human chromosome 17. Since the Wang's reference teaches the same nucleic acid derived from chromosome 17 which comprises the disclosed MRP gene of the instant application, the reference anticipates the claimed polynucleotides.

Claims 1-9 and 40-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Probst, F. J. et al. (*Science* (1998) 280, 1444-1447).

Probst et al. teach an isolated nucleic acid molecule from chromosome 11 (mouse) which comprises gene encoding a unconventional myosin protein, as applied to claims 1-9 and 40-42 of the current application.

Please note that the specification sets forth that polynucleotide encoding a myosin-related protein (MRP) of the current invention is mapped to mouse chromosome 11. Since the Probst's reference teaches the same nucleic acid derived from chromosome 11 which comprises the disclosed MRP gene of the instant application, the reference anticipates the claimed nucleic acids.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A

shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483. The examiner can normally be reached from 9:00 a.m. to 5:30 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703-308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

SWL

Samuel Wei Liu, Ph.D.

November 14, 2003

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER